

REMARKS

Reconsideration of the claims of the instant application is respectfully requested in view of the above amendments and the following remarks.

The Examiner requested the Applicants to elect between Groups I-III and also to elect a species for prosecution on merits. Applicants respectfully elect Group I (Claims 1-4, 15, and 16) without traverse. With respect to the election of species, Applicants elect antibodies which bind to the carboxy-terminus of hepcidin.

Solely to clarify possible misunderstanding between the Applicants and the Examiner, Applicants amended claims 1 and 4 to specify the sequence of hepcidin. The support for the amendment is found in Sequence Listing of the instant application.

Further, with respect to the limitation "wherein said hepcidin comprises pro-hepcidin, hepcidin or fragments thereof" in claim 15, Applicants respectfully submit that paragraph 0013 of the application as published (U.S. Pub. 20070134746) discloses different species of hepcidin, including preprohepcidin, prohepcidin and three mature forms of hepcidin which are 20, 22, and 25 amino acids long. Applicants further submit that when claim 15 is properly read in conjunction with claim 1, it is apparent that the claimed fragments of hepcidin are those which are capable of being detected by the antibodies of the instant invention.

Applicant also has amended the specification of the instant application to provide sequence identifiers.

Accordingly, the amendments to the claims and the specification do not introduce any new matter.

Applicants also respectfully submit an Information Disclosure Statement listing, *inter alia*, Ashkenazi (WO 0073454) and Nemeth (*Blood*, 101(7): 2461-63 (April 2003), pre-published on November 14, 2002).

With Respect to Ashkenazi, Applicants Clearly, Ashkenazi did not specifically disclose epitopes contained within a carboxy terminus of hepcidin amino acid sequence, e.g., amino acids 65-84. At best, Ashkenazi has disclosed a genus of epitope-containing fragments and only two representative species: from amino acid 1 to about amino acid 84 and from about amino acid 25 to about amino acid 84.

The law of genus-species anticipation states that a genus can anticipate a species only if: the species is explicitly named or if the species is “at once envisaged from the formula.” *MPEP* § 2133. Applicants submit that neither of these conditions is met in the instant case.

First, it is unarguable that Ashkenazi has not disclosed an antibody specifically binding to one or more epitopes in the carboxy-terminus of hepcidin.

Second, assuming that the polypeptides “which are sufficiently long to provide an epitope against which an antibody may be generated” are 7 amino acids long or 8 amino acids long or 9 amino acids long or 10 amino acids long, the amino acid sequence between and including amino acids 25 to 84 provides over 200 overlapping and non-overlapping epitope-containing fragments. Clearly, the epitope-containing fragment of hepcidin may be longer, which adds to the number of possible epitope-containing fragments. Further, not all of these fragments are really immunogenic to produce antibodies specific for hepcidin.

Moreover, the resulting fragments will have widely diverse chemical structures: for example, a fragment between and including amino acids 69 and 82 comprises seven cysteine residues, while any fragment between and including amino acids 1 and 68 will not contain more than two cysteine residue. A person of the ordinary skill in the art will recognize the importance of this fact because of the ability of cysteine residue to form disulfide bridges and thus to alter the structure of the epitope-containing fragment.

Thus, the fragments claimed in the instant application are neither disclosed nor “at once envisaged” in Ashkenazi.

Applicants further submit that Ashkenazi neither discloses nor suggest the use of his generically disclosed antibody for diagnosis of hepcidin.

For at least this reason, Ashkenazi neither discloses the claims of the instant invention, nor makes these claims obvious.

Nemeth discloses, *inter alia*, antibodies to carboxy terminus of hepcidin, which are capable of detecting hepcidin in urine samples. Without admitting that the disclosure of Nemeth anticipates or makes obvious the claims of the instant application, Applicants submit a copy of a sworn Affidavit by the first-named inventor (Dr. Hasan Kulaksiz).

This Affidavit establishes that the Applicants conceived the instantly claimed kit and antibodies prior to November 14, 2002. Accordingly, Nemeth is not a true prior art and a rejection of the claims of the instant application (whether on the basis of anticipation or obviousness) in view of Nemeth should not be applied.

Conclusion

In view of these amendments and remarks, Applicants believe that this application is in a condition for allowance and an early notice to this effect is earnestly solicited. If the Examiner does not believe that such action can be taken at this time or if the Examiner feels that a telephone interview is necessary or desirable, Applicants welcome the Examiner to call the undersigned at 609-844-3021.

The USPTO is authorized to charge Deposit Account No. 50-1943 for any charges in connection with this matter.

Respectfully submitted,



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